



August 20, 2021

Vermont Office of the Attorney General
109 State St
Montpelier, VT 05609
(802) 828-3171

RE: Reporting Required by Manufacturers Of New High-Cost Prescription Drugs

To whom it may concern:

Please find the required information below regarding Amivas's newly launched product, Artesunate for Injection that is used to treat severe malaria.

Manufacturer – Amivas (US), LLC, 100 Tuscanney Drive, Suite B-2, Frederick, Maryland 21702

		<u>WAC Price</u>
NDC 73607000110	Artesunate for Injection Launch date - 3/31/2021	\$9,960
NDC 73607000111	Artesunate for Injection Launch date - 3/31/2021	\$19,920

- (1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.

Marketing plan - Website and social media presence that directs inquiries to the Infectious Disease (ID) community and distributors. Targeting hospitals with calls in historic malaria case regions/countries. Achieve through analysis of historical malaria rates and data collected by the CDC, but also ID physician hospital locations available through ID societies. Attend several ID conferences held during the year. Marketing has already been initiated as official organizations/literature have adopted Artesunate for Injection as a first line therapy.

Pricing plan - The cost per 110 mg vial of IV Artesunate provided by the manufacturer, Amivas (US), LLC is set at \$4,980. Based on the studies conducted in the US, the average number of vials used per dose

(2.4 mg/kg) resulting in an estimated cost per dose of roughly \$35,403. Amivas conducted a base case cost-effectiveness analysis that had shown an indicative cost per life year saved of \$62,232 and is calculated for treatment with Artesunate for Injection compared to using IV Quinine (No longer available on the US market). Following annual 3% discounting of Life Years only as costs are all incurred in the first year, the Incremental cost-effectiveness ratio (ICER) = \$110,469 per life year saved (discounted). Overall, the pricing and availability of a formulation of Artesunate for Injection in the US will provide substantive value in access for what is considered the international standard of care for an otherwise fatal disease.

(2) The estimated volume of patients who may be prescribed the drug;

The average number of severe malaria cases is roughly 300 patients in the US on a yearly basis. This is based on historical data collected by the CDC.

(3) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and

Yes, Amivas was granted Breakthrough Therapy designation and given Priority Review for our NDA application by the FDA.

(4) The date and price of acquisition if the drug was not developed by the manufacturer

Acquisition date-2/13/2017; Acquisition cost-\$10,000 per year; Amivas has an active Cooperative Research and Development Agreement (CRADA) with the US Army. We also have a License Agreement with the US Army, whereby, the commercial rights of the product have been assigned to Amivas.

Regards,

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